

### REMARKS

Claims 21-25 and 27-37 are pending. Applicant addresses Examiner's rejections below.

#### 35 USC § 112

Examiner rejected claims 27 and 34-37 as indefinite.

Examiner contended that the term "membrane fluidity-related disorder" in claim 27 is not defined in the specification. A "membrane fluidity-related disorder" is a disorder associated with a change in the fluidity of cell membranes, and this is made clear in the specification (see, e.g., page 7, lines 17-18 ("neuropsychaitric diseases and disorders that involve altered membrane fluidity")). Applicant has described the link between disorders and membrane fluidity in the specification: "It has been reported that cell membranes in neuropsychiatric patients with certain diseases or disorders, e.g., bipolar disorder, differ from the cell membranes of healthy individuals without such diseases or disorders. For example, in bipolar patients, increased fluidity in red blood cell membranes has been observed." (page 3, lines 13-16.) Furthermore, Applicant has defined "disorder" and identified examples of membrane-fluidity disorders: "A disorder is any abnormal condition or disease, whether caused by a genetic defect, pathogen, physical trauma, chemical agent, or some other cause. Examples of membrane fluidity-related disorders include bipolar disorder, alcoholism, Alzheimer's disease, major depression, and schizophrenia." (page 4, lines 14-16; see also page 7, lines 16-20) Thus, Applicant has described in the specification the subject matter of the invention and has particularly pointed out and distinctly claimed this subject matter using the term "membrane fluidity-related disorder."

Examiner contended that the terms "candidate psychiatric drug" (claim 34), "candidate neurological drug" (claim 35), "known psychiatric drug" (claim 36), and "known neurological drug" (claim 37) are unclear. Examiner asked, "Any drug can have psychiatric or neurological side effects, so are they encompassed within the above recited limitations?" If a drug is known to have a psychiatric effect, then it is a "known psychiatric drug," and if a drug is known to have a neurological effect, then it is a "known neurological drug." If the drug is a candidate being

evaluated for potential psychiatric effects, then it is a "candidate psychiatric drug," and if the drug is a candidate for potential neurological effect, then it is a "candidate neurological drug." The fact that these terms may cover a broad range of drugs only makes them broad descriptions, which is entirely permissible, and this breadth is not to be equated with a lack of clarity or indefiniteness. See MPEP 2173.03 ("Breadth of a claim is not to be equated with indefiniteness.") Furthermore, the specification discusses testing "drug candidates." (e.g., page 5, line 11.)

Consequently, the rejections for indefiniteness should be withdrawn.

### 35 USC § 102

Examiner rejected claims 21-24, 27-28, and 30-37 as allegedly anticipated by Fishman (U.S. Patent No. 5,357,959). Examiner also rejected claims 21-23 as alleged anticipated by Carter (U.S. Patent No. 5,258,369).

Fishman discloses performing magnetic resonance imaging using a contrast agent. Fishman disclosing using standard magnetic resonance imaging techniques, which produce images that are the result of several parameters including proton density, spin-lattice relaxation time (T1), spin-spin relaxation time (T2), and flow parameters. (see col. 6, lines 11-12 ("MRI imaging is based on four important parameters. These are proton density, T<sub>1</sub>, T<sub>2</sub>, and flow parameters.")) These magnetic resonance images are not quantitative measurements of any particular relaxation parameter. Thus, Fishman does not disclose calculating the value of any relaxation parameter, i.e., T1 or T2. By contrast, as amended, claim 21 requires "calculating a first value of a relaxation parameter" and "calculating a second value of a relaxation parameter." Thus, Fishman does not disclose all limitations of claim 21 as amended. The other claims rejected as allegedly anticipated by Fishman are dependent on claim 21. Consequently, Fishman does not anticipate any of these claims.

Carter discloses using magnetic resonance imaging to study chronic fatigue syndrome. Carter discloses nothing about the details of these imaging techniques or about relaxation parameters. (see col. 6, line 59 to col. 7, line 10) As with Fishman, Carter does not disclose

calculating the value of any relaxation parameter. Since, as discussed above, claim 21 as amended requires calculating values of a relaxation parameter, Carter does not disclose all limitations of the claim. The other claims rejected as allegedly anticipated by Carter are dependent on claim 21. Therefore, Carter does not anticipate any of these claims.

### 35 USC § 103

Examiner rejected claims 21-25, 27-28, and 30-37 as obvious in light of Fishman. Examiner rejected claims 21-25 and 27-37 as obvious in light of Fishman in further view of Albert (U.S. Patent No. 5,785,953).

Examiner provided no explanation of why claim 21, or the claims dependent on claim 21 (claims 22-24, 27-28, and 30-37), were rejected as obvious in light of Fishman. Therefore, this rejection should be withdrawn with respect to those claims. Examiner's rejection of these claims as allegedly anticipated by Fishman has been addressed above.

Claim 21 also is not obvious in light of Fishman in further view of Albert. As amended, claim 21 requires "calculating a first value of a relaxation parameter" and "calculating a second value of a relaxation parameter." As explained above, Fishman does not teach or suggest calculating any values of any relaxation parameter; Fishman discloses only standard magnetic resonance imaging. Similarly, Albert discloses only standard magnetic resonance imaging methods. (see col. 11, lines 10-59.) Albert also discloses that values of relaxation parameters have been obtained in model environments: "Comparative data have been obtained which illustrate the NMR behavior of  $^{129}\text{Xe}$  in various environments. For example, various groups have determined chemical shift and relaxation rates ( $T_1$  and  $T_2$ ) for  $^{129}\text{Xe}$  in environments such as n-octanol, benzene, water and myoglobin." (see col. 14, lines 36-40.) However, Albert does not disclose calculating any values of any relaxation parameters for a mammalian subject, as required by the claim. Fishman in combination with Albert does not teach or suggest the requirements of the claim. Consequently, claim 21 is not obvious in light Fishman in combination with Albert, even assuming (without accepting) that it would be permissible to

combine these references. See MPEP 2143.03 (“To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.”).

Examiner also rejected independent claim 25 as obvious in view of Fishman alone and in further view of Albert. Applicant has amended claim 25 to require administering a neurological or psychiatric treatment to treat the disorder recited in the claim. Claim 25 as amended requires “administering a neurological or psychiatric treatment to the subject to treat [a] disorder.”

Fishman discloses use of a contrast agent. Fishman’s use of a contrast agent is not administration of a neurological or psychiatric treatment to treat a disorder. A contrast agent is used to enhance imaging, not to provide therapeutic effect. Albert discloses imaging noble gases using nuclear magnetic resonance imaging: “The present invention relates generally to techniques of nuclear magnetic resonance imaging. In particular, the present invention relates to, among other things, the detection and imaging of a noble gas by nuclear magnetic resonance imaging.” (col. 1, lines 15-19.) Albert does not teach or suggest administration of a neurological or psychiatric treatment to treat a disorder.

Neither Fishman nor Fishman in combination with Albert teach or suggest the claim limitation requiring administration of a neurological or psychiatric treatment to treat a disorder. Consequently, claim 25 is not obvious in light of Fishman or Fishman in combination with Albert, even assuming (without accepting) that it would be permissible to combine these references. See MPEP 2143.03.

Furthermore, claim 25 is not obvious in light of Fishman alone, or in further view of Albert, for an additional reason. Claim 25 recites administering pre-treatment and post-treatment challenges to a subject. Examiner contends “that the recitation of a pre-treatment challenge does not exclude any normal physiological activity of subject patients,” citing “breathing or even eating food” as possible pre-treatment challenges. However, this does not give the claims their broadest reasonable interpretation consistent with the specification. To the contrary, it effectively reads the limitations “administering to the subject a pre-treatment challenge that alters a physical or chemical property of cell membranes in the brain of the subject” and

“administering to the subject a post-treatment challenge that alters a physical or chemical property of cell membranes in the brain of the subject” out of the claims.

A pre-treatment challenge or post-treatment challenge cannot be “any normal physiological activity,” as Examiner contends. A “normal physiological activity” is not administered, as required by the claims. For example, Examiner points to breathing as a possible challenge, but breathing is not administered. It simply happens as a function of survival. Consistent with the specification, the plain meaning of “administering” in the context of administering a challenge means “to give or apply in a formal way.” The American Heritage® Dictionary of the English Language (4<sup>th</sup> ed. 2000). “Breathing” and “eating” are not given or applied in a formal way. As discussed in the specification, administering a challenge involves giving a patient an effective amount of a compound. (see, e.g., page 4, lines 18-24). This could be accomplished through ingesting the compound alone or through a certain dietary prescription. Fishman does not teach or suggest any administration of a challenge, let alone administration of both pre-treatment and post-treatment challenges.

#### New claim

Applicant has added claim 38, which is dependent on claim 25. This claim is supported by, e.g., page 3, lines 1-2 and page 11, lines 4-8. No new matter is added. This claim is allowable for at least the reasons discussed above with respect to claim 25.

Applicant submits that all pending claims are in condition for allowance for the reasons discussed above. Applicant has not addressed all of Examiner's positions because Applicant believes its amendments and remarks have made it unnecessary to address certain positions. In doing so, Applicant does not imply agreement with these positions and does not intend any surrender of rights.

Enclosed is a \$210.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050 (reference 04843-033001).

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Respectfully submitted,

Date: \_\_\_\_\_

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